the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 0.2 part per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(2) 2 parts per million in animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals.

(3) 10 parts per million in paper food-packaging material intended for or used with finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled ''Analytical Methodology for Polychlorinated Biphenyls, February 1973'' for determining compliance with the tolerances established in this section is available from the Dockets Management Branch, Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

[42 FR 52821, Sept. 30, 1977, as amended at 46 FR 8460, Jan. 27, 1981; 59 FR 14365, Mar. 28, 1994]

## Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances [Reserved]

## Subpart D—Naturally Occurring Poisonous or Deleterious Substances [Reserved]

# PART 510—NEW ANIMAL DRUGS

### Subpart A—General Provisions



### Subpart B—Specific Administrative Rulings and Decisions



### Subpart C [Reserved]

### Subpart D—Records and Reports



### Subpart E—Requirements for Specific New Animal Drugs



### Subpart F—Animal Use Exemptions From Certification and Labeling Requirements



### Subpart G—Sponsors of Approved Applications



AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

SOURCE: 40 FR 13807, Mar. 27, 1975, unless otherwise noted.

## Subpart A—General Provisions

### § 510.3 Definitions and interpretations.

As used in this part:

(a) The term *act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 *et seq.*, as amended; 21 U.S.C. 321–392).

(b) *Department* means the Department of Health and Human Services.

(c) *Secretary* means the Secretary of Health and Human Services.

(d) *Commissioner* means the Commissioner of Food and Drugs.

(e) *Person* means individuals, partnerships, corporations, and associations.

(f) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) The term *new animal drug* means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed:

(1) The composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a *new animal drug* if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) The composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(h) The term *animal feed* means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(i) The newness of an animal drug, including a new animal drug intended for use in or on animal feed, may arise by reason of: (1) The newness for its intended drug use of any substance of which the drug is comprised, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component; (2) the newness for its intended drug use of a combination of two or more substances, none of which is itself a new animal drug; (3) the newness for its intended drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new animal drug; (4) the newness for its intended drug use in a different species of animal; (5) the newness of its intended drug use in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the animal body, even though such drug is not a new animal drug when used in another disease or to affect another structure or function of the body; or (6) the newness of a dosage, or method or duration of administration or application, or any other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug or animal feed containing such drug when used in another dosage, or another method or duration of administration or application, or different condition, is not a new animal drug.

(j) *Animals used only for laboratory research* and *laboratory research animals* mean individual animals or groups of animals intended for use and used solely for laboratory research purposes, regardless of species, and does not include animals intended to be used for any food purposes or animals intended to be kept as livestock.

(k) The term *sponsor* means the person responsible for an investigation of a new animal drug, including responsibility for compliance with applicable provisions of the act and regulations. The *sponsor* may be an individual, partnership, corporation, or Government agency or may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new animal drugs.

(l) *Designated journal(s)* means journals listed in § 510.95.

[40 FR 13807, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985; 54 FR 22741, May 26, 1989]

### § 510.4 Biologics; products subject to license control.

An animal drug produced and distributed in full conformance with the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 *et seq.*) and any regulations issued thereunder shall not be deemed to be subject to section 512 of the Federal Food, Drug, and Cosmetic Act.

### § 510.7 Consignees of new animal drugs for use in the manufacture of animal feed.

(a) A new animal drug intended for use in the manufacture of animal feed shall be deemed to be unsafe unless at the time of its removal from the establishment of a manufacturer, packer, or distributor of such drug, such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or a notice from the Secretary, to the effect that with respect to the use of such drug in animal feed the consignee:

(1) Is the holder of an approved application under § 514.2 of this chapter; or

(2) Will, if the consignee is not a user of the drug, ship such drug only to a holder of an approved application under § 514.2 of this chapter.

(b) The requirements of paragraph (a) of this section do not apply:

(1) Where such drugs are intended for export and/or

(2) When the use of such drug in the manufacture of a finished feed has been exempted from the requirements of section 512(m) of the act under the conditions specified by regulations published in part 558 of this chapter.

### § 510.45 Packaging requirements for drugs for animal use.

The packaging requirements for antibiotic drugs for veterinary use are described under § 432.1 of this chapter, except that antibiotic drugs for veterinary use need not be packaged for dispensing in containers of colorless, transparent glass.

### § 510.95 Designated journals.

The following journals are available to the Food and Drug Administration and thus permit waiving of the submission of reprints and summaries covering reports contained in these journals to the extent that such requirements are waived in the regulations in this part:

All Pet's Magazine (Jersey City).
American Journal of Veterinary Research (Chicago).
Animal Health (Journal of the Animal Health Trust) (London).
Animal Nutrition & Health (Sausalito, CA).
Animal Production (Edinburgh).
Avian Diseases (Amherst).
British Poultry Science (Edinburgh).
Canadian Journal of Comparative Medicine and Veterinary Science (Gardenvale, Quebec).
Canadian Veterinary Journal (Guelph, Ontario).
Cornell Veterinarian (Ithaca).
Experimental Parasitology (New York).
The Feed Bag (Milwaukee).
Feedstuffs (Minneapolis).
Hoard's Dairyman (Fort Atkinson).
Journal of the American Veterinary Medical Association (Chicago).
Journal of Animal Science (Albany).
Journal of Dairy Science (Champaign).
Journal of Economic Entomology (Baltimore).
Journal of Small Animal Practice (London).
Modern Veterinary Practice (formerly North American Veterinarian) (Wheaton, IL).
National Hog Farmer (Grundy Center, IA).
New Zealand Veterinary Journal (Wellington).
Poultry Science (Guelph, Ontario).
Praktische Tierarzt (Postfach, Germany).
Research in Veterinary Science (Chicago).
Small Animal Clinician (Kansas City, MO).
Veterinaermedizin (Konstanz, Germany).
Veterinarian (London).
Veterinarian (International) (New York).
The Veterinary Bulletin (Farnham Royal, England).
Veterinary Medicine (Kansas City, MO).
Veterinary Record (Croydon, England).
Zentralblatt Fuer Veterinaermedizin Zentr. Veterinaermed (Berlin).

[40 FR 13807, Mar. 27, 1975, as amended at 50 FR 7517, Feb. 22, 1985]

## Subpart B—Specific Administrative Rulings and Decisions

### § 510.105 Labeling of drugs for use in milk-producing animals.

(a) Part 540 of this chapter provides for new animal drugs intended for

intramammary use in animals and includes conditions of use intended to prevent the contamination of milk from the use of such drugs.

(b) Preparations containing antibiotics and other potent drugs labeled with directions for use in milk-producing animals will be misbranded under section 502(f)(2) of the act unless their labeling bears appropriate warnings and directions for use to avoid adulteration of milk under section 402(a)(2)(D) of the act.

(c) It is the position of the Food and Drug Administration that the labeling for such preparations should bear a clear warning that either:

(1) The article should not be administered to animals producing milk, since to do so would result in contamination of the milk; or

(2) The label should bear the warning, ''Milk that has been taken from animals during treatment and within ——— hours (——— milkings) after the latest treatment must not be used for food,'' the blanks to be filled in with the number of hours (not to exceed 96) and milkings that the manufacturer has determined by appropriate investigation is needed to insure that the milk will not carry residues resulting from use of the preparation. If the use of the preparation as recommended does not result in contamination of the milk, neither of the above warning statements is required.

### § 510.106 Labeling of antibiotic and antibiotic-containing drugs intended for use in milk-producing animals.

Whenever the labeling of an antibiotic drug included in the regulations in this chapter suggests or recommends its use in milk-producing animals, the label of such drugs shall bear either the statement ''Warning: Not for use in animals producing milk, since this use will result in contamination of the milk'' or the statement ''Warning: Milk that has been taken from animals during treatment and for — hours (—— milkings) after the latest treatment must not be used for food'', the first blank being filled in with the figure, which shall not be greater than 96, that the Commissioner has authorized the manufacturer of the drug to use, and the second figure shall be the first number divided by 12. The Commissioner shall determine what such figures shall be from information submitted by the manufacturer and which the Commissioner considers is adequate to prove that period of time after the latest treatment that the milk from treated animals will contain no residues from use of the preparation. If the Commissioner determines from the information submitted that the use of the antibiotic drug as recommended does not result in its appearance in the milk, he may exempt the drug from bearing either of the above warning statements.

### § 510.110 Antibiotics used in food-producing animals.

(a) The Food and Drug Administration in the interest of fulfilling its responsibilities with regard to protection of the public health has requested an evaluation of the public health aspects of the use of antibiotics in veterinary medical and nonmedical uses. There is particular concern with regard to the potential hazards associated with the extensive use of antibiotics administered to food-producing animals. Accordingly, an ad hoc committee on the Veterinary Medical and Nonmedical Uses of Antibiotics was established by the Food and Drug Administration to study and advise the Commissioner of Food and Drugs on the uses of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to their safety and effectiveness.

(b) Based upon an evaluation of the conclusions of said Committee and other relevant material, § 510.112 was published in the FEDERAL REGISTER of August 23, 1966 (31 FR 11141), asking sponsors of drugs containing any antibiotic intended for use in food-producing animals to submit data to establish whether such antibiotic and its metabolites are present as residues in edible tissues, milk, and eggs from treated animals. The data on the residues of antibiotics in milk from intramammary infusion preparations were requested within 60 days and the data on all other products were requested within 180 days following the

date of publication of § 510.112 in the FEDERAL REGISTER.

(c) An evaluation of the data now available shows that use of many antibiotic preparations cause residues in edible products of treated animals for varying and, in some cases, for long periods of time following the last administration. Because of the accumulation of new information with regard to the development of resistance of bacteria to antibiotics, the ability of bacteria to transfer this resistance, and the development of sensitivity to antibiotics in humans, unauthorized and unsafe residues of antibiotics cannot be permitted in food obtained from treated animals.

(d) Based on evaluation of information available, including the conclusions of the aforementioned ad hoc Committee, the Commissioner concludes that antibiotic preparations intended for use in food-producing animals, other than topical and ophthalmic preparations, are not generally recognized among qualified experts as having been shown to be safe for their intended use(s) within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act.

(e) Therefore, all exemptions from the provisions of section 409 of the act for use of antibiotics in food-producing animals based on sanctions or approvals granted prior to enactment of the Food Additives Amendment of 1958 (Pub. L. 85–929; 72 Stat. 1784) will be revoked and the uses which are concluded to be safe will be covered by food additive regulations. On those products for which there are inadequate residue data, actions will be initiated to amend or revoke antibiotic regulations under the provisions of section 507 of the act, or to withdraw approval of new-drug applications under the provisions of section 505 of the act. Antibiotic preparations, other than those for topical and ophthalmic application in food-producing animals, which are not covered by food additive regulations will be subject to regulatory action within 180 days after publication of the forthcoming revocation order.

(f) Because of the variation in the period of time that antibiotic residues may remain in edible products from treated animals, all injectable, intramammary infusion, intrauterine, and oral preparations (except certifiable antibiotics), including medicated premixes intended for use in food-producing animals, are deemed to be new drugs as well as food additives. An antibiotic application (see § 431.50 of this chapter) will be required for all medicated premixes containing certifiable antibiotics.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989]

### § 510.112 Antibiotics used in veterinary medicine and for nonmedical purposes; required data.

(a) An ad hoc committee, Committee on the Veterinary Medical and Nonmedical Uses of Antibiotics, was formed by the Food and Drug Administration to study, and advise the Commissioner on, the use of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to the safety and effectiveness of such substances. A copy of the report may be obtained from the Food and Drug Administration, Office of Public Affairs, Room 15–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

(b) On the basis of the report of the Committee and other information, sponsors of drugs containing any antibiotic intended for use in food-producing animals shall submit data for determining whether or not such antibiotics and their metabolites are present as residues in edible tissues, milk, and eggs from treated animals; however, in the case of a drug for which such data have already been submitted and for which a regulation has been promulgated under section 409 of the act, only such data as has been accumulated since the issuance of the regulation need be submitted.

(c) The required data shall be submitted within 180 days of the date of publication of this section in the FEDERAL REGISTER; except that in the case of data on intramammary infusion preparations the data shall be submitted within 60 days of such publication. Data demonstrating the absence in

milk of residues of intramammary infusion preparations when used as directed in their labeling are needed within the 60-day period because of the importance of milk in the human diet.

(d) Regulatory proceedings including revocation of prior sanctions, or actions to suspend or amend new drug or antibiotic approvals granted prior to passage of the Food Additives Amendment of 1958 (72 Stat. 1784), may be initiated with regard to the continued marketing of any antibiotic preparation on which the required information is not submitted within the period of time prescribed by paragraph (c) of this section.

(e) Questions relating to the acceptability of proposed research protocols and assay methods for determining the amount of antibiotic residues in food should be directed to the Director, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

[40 FR 13807, Mar. 27, 1975, as amended at 46 FR 8460, Jan. 27, 1981; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992]

## Subpart C [Reserved]

## Subpart D—Records and Reports

### § 510.300 Records and reports concerning experience with new animal drugs for which an approved application is in effect.

(a) On receiving notification that an application submitted pursuant to § 514.1 of this chapter for a new animal drug is approved, the applicant shall establish and maintain such records and make such reports as are specified in this section to facilitate a determination as to whether there may be grounds for suspending or withdrawing approval of the application or whether any applicable regulation should be amended or repealed. The applicant shall maintain adequately organized and indexed files containing full reports of information pertinent to the safety or effectiveness of the new animal drug that have not previously been submitted as part of his application for the drug and which are received or otherwise obtained by him from any source, as follows:

(1) Unpublished reports of clinical or other animal experience, studies, investigations, and tests conducted by the applicant or reported to him by any person involving the new animal drug that is the subject of the application or any related drugs. An adequate summary and bibliography of reports in the scientific literature would ordinarily suffice. (The application must identify at the time of each report submission, each drug he considers related to the subject drug.)

(2) Experience, investigations, studies, or tests involving the chemical or physical properties or any other properties of the new animal drug, such as its behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effect of microorganisms on the drug.

(3) For information required by this section, adequate identification of its source, when known, including the name and post office address of the person who furnishes such information.

(4) Copies of all mailing pieces and other labeling, and, if it is a prescription new animal drug, all advertising other than that contained in the application used in promoting the drug, and copies of the currently used package labeling that gives full information for use of the drug whether or not such labeling is contained in the application.

(5) Information concerning the quantity of the new animal drug distributed in a manner and form that facilitates estimates of the incidence of any adverse effects reported to be associated with the use of the drug. This does not require disclosure of financial, pricing, or sales data.

(6) Information concerning any previously unreported changes from the conditions described in an application conforming to the conditions of § 514.8(a)(5) of this chapter.

(b) The applicant shall submit to the Food and Drug Administration copies of the records and reports described in paragraph (a) of this section, except routine assay and control records, appropriately identified with the new animal drug application(s) to which they relate, as follows:

(1) Immediately upon receipt by the applicant, complete records or reports

covering information of the following kinds:

(i) Information concerning a mixup in the new animal drug or its labeling with another article.

(ii) Information concerning any bacteriological or significant physical or other change or deterioration in the new animal drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application.

(2) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records of reports concerning any information of the following kinds:

(i) Information concerning any unexpected side effects, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical use, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. *Unexpected* as used in this subdivision refers to conditions or developments not previously submitted as part of the new animal drug application, or conditions and developments occurring at a rate higher than that shown by information previously submitted as part of the application.

(ii) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activities.

(3) When mailing pieces, any other labeling, and advertising are devised for promotion of the new animal drug, specimens shall be submitted at the time of initial dissemination of such labeling and at the time of initial publication of any advertisement for a prescription drug. Mailing pieces and labeling designed to contain samples of a drug shall be complete except for the omission of the drug.

(4) All the kinds of information described in paragraph (a) of this section, other than that submitted under the provisions of paragraphs (b) (1), (2), and (3) of this section, shall be submitted as follows unless otherwise ordered in a written communication from the Commissioner:

(i) At intervals within 6 months beginning with the date of approval of the new animal drug application during the first year following such date, and at yearly intervals thereafter.

(ii) Whenever an applicant is required to submit reports under the provisions of paragraph (b)(4)(i) of this section with respect to more than one approved application for preparations containing the same new animal drug so that the same item(s) of information is (are) required to be reported for more than one application, he may elect to submit as a part of the report for one such application all the information common to such applications in lieu of reporting separately and repetitively on each. The applicant shall state when this is done and identify all the new animal drug applications for which the reports are submitted.

(iii) The submitted copies of records and reports shall include all the required information that was received or otherwise obtained by the applicant during the designated intervals.

(5) On written order of the Commissioner, within the time stated in such order or agreed to by the applicant and the Commissioner, any designated records or reports containing the kinds of information described in this section shall be submitted.

(c) The applicant shall, upon request of any properly authorized officer or employee of the Department at reasonable times, permit such officers to have access to and copy and verify any records and reports established and maintained under the provisions of this section.

(d) If the Food and Drug Administration finds that the applicant has failed to establish a system for maintaining required records or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with the provisions of this section, or that the applicant has refused to permit access to or copying of, or verification of such records or reports, the Commissioner shall give the applicant notice and opportunity for a hearing on the question of whether to

withdraw the approval of the application, as provided in § 514.200 of this chapter.

(e) Upon written request of the applicant stating reasonable grounds therefor, the Commissioner will make available any information in possession of the Food and Drug Administration of the kinds the applicant is required to maintain under the provisions of this section, except information readily available to the applicant from other sources or information which the Commissioner concludes is confidential.

(f) The *applicant* required to establish and maintain records and make reports required by this section includes any person whose name appears on the labeling of the drug as its manufacturer, packer, or distributor under an approval or who is engaged in the manufacturing, processing, packing, or labeling of the drug under an approval of the new animal drug application or any supplement to it; however, to avoid unnecessary duplication in the submission of reports, any such applicant's obligation to submit a report may be met by its submission on his behalf, designated as such, by another person responsible for reporting.

### § 510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved application is in effect.

Records and reports of clinical and other experience with the new animal drug will be maintained and reported, appropriately identified with the new animal drug application(s) to which they relate, to the Center for Veterinary Medicine in duplicate in accordance with the following:

(a) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(1) Information concerning any mixup in the new animal drug or its labeling with another article.

(2) Information concerning any bacteriological, or any significant chemical, physical, or other change or deterioration in the drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application.

(b) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records or reports concerning any information of the following kinds:

(1) Information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. *Unexpected* as used in this paragraph refers to conditions or developments not previously submitted as part of the new animal drug application or not encountered during clinical trials of the drug, or conditions or developments occurring at a rate higher than shown by information previously submitted as part of the new animal drug application or at a rate higher than encountered during such clinical trials.

(2) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activity.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989]

### § 510.302 Reporting forms.

(a) The information described in § 510.300, except that described in paragraphs (b) (1) and (2) of that section, shall be submitted appropriately identified with the new animal drug application(s) to which they relate in duplicate on Form FD–2301 ''Transmittal of Periodic Reports and Promotional Material for New Animal Drugs.''

(b) All adverse experiences with new animal drugs as described in § 510.300(b)(2) or § 510.301(b) whether or not related to a required periodic report submitted on a Form FD–2301, shall be reported on Form FD–1932 ''Adverse Drug Reaction'' (except as provided in paragraph (c) of this section). Reports of adverse drug experiences may be submitted initially in the form of a written communication, but

any such communication shall be followed promptly (but not necessarily within the prescribed 15 working days) by a completed Form FD–1932. A separate ''Adverse Drug Reaction'' form should be submitted for each patient where feasible.

(c) In lieu of Form FD–1932 the holder of an approved new animal drug application may submit:

(1) A computerized report if the information contained therein and the sequence in which it is presented are equivalent to that required by Form FD–1932 and the report is submitted in duplicate. Such reports will require initial approval by the Food and Drug Administration prior to use; and

(2) Copies of reports of reactions appearing in the published scientific literature may be submitted.

(d) Forms FD–1932 and FD–2301, with instructions for their use, may be obtained from the Food and Drug Administration, Department of Health and Human Services, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

[40 FR 13807, Mar. 27, 1975, as amended at 41 FR 35844, Aug. 25, 1976; 54 FR 18280, Apr. 28, 1989; 57 FR 6475, Feb. 25, 1992]

### § 510.305 Maintenance of copies of approved applications for animal feed bearing or containing new animal drugs.

Each applicant shall maintain in a single accessible location on the premises of each establishment to which an approved medicated feed application (Form FDA 1900) or supplemental application applies either:

(a) A copy of the approved medicated feed application (Form FDA 1900) and a sample of the approved labeling; or

(b) Identification of the approved medicated feed application in a single file or in a single readable document that includes:

(1) The application number and date of its approval;

(2) The name(s) of the premix(es) and the concentration of the drug(s) contained in the premix(es);

(3) The name(s) of the approved manufacturer(s) of the premix(es);

(4) The concentration of the drug(s) in the finished medicated feed; and

(5) A sample of the approved labeling.

[41 FR 36203, Aug. 27, 1976, as amended at 51 FR 7391, Mar. 3, 1986]

## Subpart E—Requirements for Specific New Animal Drugs

### § 510.410 Corticosteroids for oral, injectable, and ophthalmic use in animals; warnings and labeling requirements.

(a) The Food and Drug Administration has received reports of side effects associated with the oral, injectable, and ophthalmic use of corticosteroid animal drugs. The use of these drugs administered orally or by injection has resulted in premature parturition when administered during the last trimester of pregnancy. Premature parturition may be followed by dystocia, fetal death, retained placenta, and metritis. Additionally, corticosteroids used in dogs, rabbits, and rodents during pregnancy have produced cleft palate in offspring. Use in dogs has resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca. Drugs subject to this section are required to carry the veterinary prescription legend and are subject to the labeling requirements of § 201.105 of this chapter.

(b) In view of these potentially serious side effects, the Food and Drug Administration has concluded that the labeling on or within packaged corticosteroid-containing preparations intended for animal use shall bear conspicuously the following warning statement:

*Warning:* Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

[49 FR 48535, Dec. 13, 1984]

### § 510.440 Injectable iron preparations.

There has been an increasing interest in the use of injectable iron compounds for the prevention or treatment of iron-deficiency anemia in animals. Although some such preparations have been shown to be safe, such articles are regarded as new animal drugs within the meaning of the Federal Food, Drug, and Cosmetic Act. Accordingly, an approved new animal drug application is required prior to the marketing of such preparations within the jurisdiction of the act. In addition to the need for demonstrating the safety of such articles, the labeling of such preparations should not only recommend appropriate dosages of iron but also declare the amount (in milligrams) of available iron (Fe) per milliliter of the subject product.

### § 510.455 New animal drug requirements regarding free-choice administration in feeds.

(a) For the purpose of this section, free-choice administration of animal drugs in feeds involves feeds that are placed in feeding or grazing areas and are not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. Such methods of administering drugs include, but are not limited to, medicated blocks (agglomerated feed compressed or rendered into a solid mass and cohesive enough to hold its form), mineral mixes, and liquid feed tank supplements (''lick tank'' supplements) containing one or more animal drugs. The manufacture of medicated free-choice feeds is subject to the current good manufacturing practice regulations for medicated feeds.

(b) The Food and Drug Administration has concluded that there are questions about the safety and effectiveness of drugs when administered in free-choice feeds. Therefore, such methods of administration cause the drugs so administered to be new animal drugs, for which approved new animal drug applications (NADA's) are required. (See § 510.3(i)). In addition, the exemption from the requirement of an approved medicated feed application provided in § 558.4 of this chapter does not apply to any free-choice medicated feed.

(c) An NADA or supplemental NADA for products for free-choice feeding submitted for approval under section 512(b) of the act shall provide for:

(1) The manufacture of a finished product for the free-choice administration of a new animal drug. Such an approval will not provide a basis upon which an application can be approved under section 512(m) of the act; or

(2) The manufacture of a Type A medicated article for use in the subsequent manufacture of a free-choice medicated feed. The approved NADA will provide a basis upon which an application can be approved under section 512(m) of the act. Data for a specific free-choice product may, if desired, be generated and submitted to the Food and Drug Administration by the manufacturer of the free-choice feed in the form of a master file which can be referenced in the NADA or supplemental NADA submitted by the new animal drug sponsor.

(d) Approval of the NADA or supplemental NADA submitted under paragraph (c) of this section will be reflected in a regulation in part 558 of this chapter published under section 512(i) of the act. The regulation will either state the formulation of the approved free-choice product or specify the specific free-choice administration products in which the drug is approved for use. If the approval is for a Type A medicated article, the regulation in part 558 of this chapter will indicate that each use of the Type A medicated article in a free-choice product must be the subject of an approved supplemental NADA.

(e) An application submitted under section 512(m) of the act to provide for manufacture of a specific free-choice feed from an approved Type A medicated article will be approved if, in addition to the information required by the medicated feed application, it includes a reference to the exact formula of the product to be manufactured as follows:

(1) The formula is the same as the one published in the new animal drug regulations; or

(2) The data in a master file have been referenced in an NADA or supplemental NADA; and

(3) Use of the Type A medicated article in the specific formulation has been approved on the basis that:

(i) The formula is the same as the one for which acceptable data have been submitted in a master file by the medicated feed applicant; or

(ii) The medicated feed applicant has written authority to reference a master file that has acceptable data for the formula in question.

(Approved by the Office of Management and Budget under control number 0910–0205)

[51 FR 19827, June 3, 1986]

## Subpart F—Animal Use Exemptions From Certification and Labeling Requirements

### § 510.515 Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act.

Animal feeds that bear or contain penicillin, chlortetracycline, feed grade zinc bacitracin, and bacitracin methylene disalicylate, with or without added suitable nutritive ingredients are exempt from the certification requirements of section 512 of the act provided they are the subject of and in compliance with regulations for their use in this subchapter E, part 558 of this chapter, or any one of the paragraphs of this section:

(a) Where indicated in paragraph (b) of this section it is manufactured with or without one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(1) Arsanilic acid: Not less than 0.005 percent and not more than 0.01 percent.

(2) Sodium arsanilate: Not less than 0.005 percent and not more than 0.01 percent.

(3) 3-Nitro-4-hydroxyphenylarsonic acid: Not less than 0.0025 percent and not more than 0.0075 percent except in chicken or turkey feed which shall contain not less than 0.0025 percent and not more than 0.005 percent.

(b) It is intended for use in any one of the following conditions set forth in this paragraph:

(1) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection), infectious sinusitis, and blue comb (nonspecific infectious enteritis) in poultry and/or bacterial swine enteritis; its labeling bears adequate directions and warnings for such use; and it contains, per ton of feed, the equivalent of 100 grams of penicillin. When intended for uses specified in this paragraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section.

(2) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) and infectious sinusitis in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 0.1 percent para-aminobenzoic acid or the sodium or potassium salt or para-aminobenzoic acid.

(3)–(29) [Reserved]

(c) It is intended for use as follows:

| Product | Species | Use levels | Indications for use |
|---|---|---|---|
| 1. Nicarbazin | Chickens | 0.01 to 0.02 percent | For use in the prevention of outbreaks of coccidiosis in poultry flocks; growth promotion and feed efficiency. |
| | do | 2.4 to 50 g/ton | |
| 2. Nicarbazin | do | 0.01 to 0.02 percent | Do. |
| Bacitracin methylene disalicylate. | do | 4 to 50 g/ton. | |
| 3. Nicarbazin | do | 0.01 to 0.02 percent | For use as an aid in the prevention of coccidiosis in poultry flocks; growth promotion and feed efficiency; improving pigmentation. |
| Bacitracin methylene disalicylate. | do | 4 to 50 g/ton. | |
| 3-Nitro-4-hydroxyphenylarsonic acid. | do | 0.0025 to 0.005 percent. | |
| 4. Nicarbazin | do | 0.01 to 0.02 percent | Do. |
| Procaine penicillin | do | 2.4 to 50 g/ton. | |
| 3-Nitro-4-hydroxyphenylarsonic acid. | do | 0.0025 to 0.005 percent. | |

| Product | Species | Use levels | Indications for use |
|---|---|---|---|
| 5. Chlortetracycline ..... | Swine ..... | 10 to 50 g/ton ..... | Enhancement of growth and feed efficiency. |
| Arsanilic acid ..... | .....do ..... | 0.005 to 0.01 percent. | |

[41 FR 8299, Feb. 25, 1976, as amended at 41 FR 11011, Mar. 15, 1976; 42 FR 18614, Apr. 8, 1977; 47 FR 42102, Sept. 24, 1982; 47 FR 51563, Nov. 16, 1982; 56 FR 41912, Aug. 23, 1991; 58 FR 30119, May 26, 1993; 61 FR 35950, July 9, 1996]

## Subpart G—Sponsors of Approved Applications

### § 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(a) Section 512(i) of the act requires publication of names and addresses of sponsors of approved applications for new animal drugs.

(b) In this section each name and address is identified by a numerical drug labeler code. The labeler codes identify the sponsors of the new animal drug applications associated with the regulations published pursuant to section 512(i) of the act. The codes appear in the appropriate regulations and serve as a reference to the names and addresses listed in this section. The drug labeler code is established pursuant to section 510 of the act.

(c) The names, addresses, and drug labeler codes of sponsors of approved new animal drug applications are as follows:

(1) ALPHABETICAL LISTING OF SPONSORS

| Firm name and address | Drug labeler code |
|---|---|
| Abbott Laboratories, North Chicago, IL 60064 .... | 000074 |
| ADM Animal Health & Nutrition Div., P.O. Box 2508, Fort Wayne, IN 46801–2508 ..... | 017519 |
| Affiliated Laboratories Division, Whitmoyer Laboratories, Inc., 19 North Railroad St., Myerstown, PA 17067 ..... | 011825 |
| Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464 ..... | 024174 |
| Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503 ..... | 057561 |
| Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112 ..... | 017762 |
| Carl S. Akey, Inc., P.O. Box 607, Lewisburg, OH 45338 ..... | 017790 |
| Akzo Nobel Surface Chemistry AB, Box 851, S–44485 Stenungsund, Sweden ..... | 063765 |
| Albers Milling Co., Carnation Bldg., 5045 Wilshire Blvd., Los Angeles, CA 90036 ..... | 017826 |
| Albion Laboratories, Inc., 101 North Main, Clearfield, UT 84015 ..... | 011485 |

(1) ALPHABETICAL LISTING OF SPONSORS—Continued

| Firm name and address | Drug labeler code |
|---|---|
| Allied Pharmacal, Division of K.C. Pharmacal, Inc., 1234 Clay St., North Kansas City, MO 64116 ..... | 012983 |
| Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024 ..... | 046573 |
| Alstoe, Ltd., Animal Health, Granary Chambers, 37–39 Burton St., Melton Mowbray, Leicestershire LE13 1AF, England ..... | 062408 |
| Altana Inc., 60 Baylis Rd., Melville, NY 11747 ... | 025463 |
| American Cyanamid, Division of American Home Products, P.O. Box 1339, Fort Dodge, IA 50501 ..... | 010042 |
| American Veterinary Products, Inc., 749 South Lemay, Suite A3–231, Fort Collins, CO 80524 | 045984 |
| Anika Research, Inc., 160 New Boston St., Woburn, MA 01801 ..... | 060865 |
| Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006 ..... | 000864 |
| Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052 ..... | 051212 |
| Ausa International, Inc., Rt. 8, P.O. Box 324–12, Tyler, TX 75703 ..... | 059521 |
| Ayerst Laboratories, Division of American Home Products Corp., 685 Third Ave., New York, NY 10017 ..... | 000046 |
| Balfour Guthrie & Co., Ltd., 315 North H St., Fresno, CA 93701 ..... | 043728 |
| Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee, Mission, KS 66201 .. | 000859 |
| Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407 ..... | 000332 |
| Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44333–2435 ..... | 051359 |
| Biopure Corp., 11 Hurley St., Cambridge, MA 02141 ..... | 063075 |
| Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Highway, St. Joseph, MO 64502 .... | 000010 |
| Bristol Laboratories, Division of Bristol-Myers Co., P.O. Box 4755, Syracuse, NY 13221–4755 ..... | 000015 |
| Carnation Co., 5045 Wilshire Blvd., Los Angeles, CA 90036 ..... | 047019 |
| Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland ..... | 061651 |
| Chemdex, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215 ..... | 017287 |
| Combe, Inc., 1101 Westchester Ave., White Plains, NY 10604 ..... | 011509 |
| ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105 ..... | 021091 |
| Cooper U.S.A., Inc., P.O. Box 12338, Research Triangle Park, NC 27709 ..... | 011492 |
| Cooperative Research Farms, Box 69, Charlotteville, NY 12036 ..... | 051267 |
| Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland ..... | 061623 |
| Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501 ..... | 046987 |
| Custom Feed Services Corp., 2100 N. 13th St., Norfolk, NE 68701 ..... | 017473 |
| Cutter Laboratories, Inc., Fourth and Parker St., Berkeley, CA 94710 ..... | 000161 |

(1) ALPHABETICAL LISTING OF SPONSORS—Continued

| Firm name and address | Drug labeler code |
|---|---|
| Cyanamid Agricultural de Puerto Rico, Inc., P.O. Box 243, Manati, PR 00701 | 043781 |
| Danbury Pharmacal, Inc., 131 West St., Danbury, CT 06810 | 000591 |
| Dawes Laboratories, Inc., 450 State St., Chicago Heights, IL 60411 | 024264 |
| Delmarva Laboratories, Inc., 2200 Wadebridge Rd., P.O. Box 525, Midlothian, VA 23113 | 059079 |
| Deprenyl Animal Health, Inc., 7101 College Blvd., Suite 580, Overland Park, KS 66210 | 063248 |
| Diamond Shamrock Corp., Nutrition & Animal Health Div., 1100 Superior Ave., Cleveland, OH 44114 | 025001 |
| DuPont Merck Pharmaceutical Co., DuPont Merck Plaza, MR2117, Wilmington, DE 19805 | 000056 |
| Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285 | 000986 |
| Endo Pharmaceuticals, Inc., 223 Wilmington West Chester Pike, Chadds Ford, PA 19317 | 060951 |
| Eon Labs Manufacturing, Inc. 227-15 North Conduit Ave., Laurelton, NY 11413 | 000185 |
| Evsco Pharmaceuticals, An Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310 | 017030 |
| Farmers Feed & Supply Co., Ninth St. at Northwestern Tracks, Tipton, IA 52772 | 043744 |
| Farmland Industries, Inc., Kansas City, MO 64116 | 021676 |
| Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928 | 017135 |
| Feed Products, Inc., 1000 West 47th Ave., Denver, CO 80211 | 013959 |
| Feed Service Co., Inc., 303 Lundin Blvd., P.O. Box 698, Mankato, MN 56001 | 030841 |
| John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611 | 058034 |
| Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234 | 015565 |
| Fort Dodge Animal Health, A Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501 | 053501 |
| Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501 | 000856 |
| Franklin Laboratories, Inc., P.O. Box 717, Fort Dodge, IA 50501 | 010290 |
| Fujisawa USA, Inc., Deerfield, IL 60015–2548 | 000469 |
| Furst-McNess Co., Freeport, IL 61032 | 010439 |
| Gland-O-Lac Co., 1818 Leavenworth St., Omaha, NE 68102 | 043735 |
| Global Pharmaceutical Corp., Castor and Kensington Aves., Philadelphia, PA 19124 | 000115 |
| H. Clay Glover Co., Inc., 1001 Franklin Ave., Garden City, NY 11530 | 010471 |
| Golden Sun Feeds, Inc., 111 South Fifth St., Estherville, IA 51334 | 021780 |
| Gooch Feed Mill Corp., 540 South St., Lincoln, NE 68501 | 021798 |
| Michael Gordon, Inc., P.O. Box 8091, San Francisco, CA 94118 | 049047 |
| Gossett Nutrition, Inc., 1676 Cascade Dr., Marion, OH 43302 | 050972 |
| Grain Processing Corp., Muscatine, IA 52761 | 022591 |
| G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201 | 010515 |
| Halocarbon Laboratories, Division of Halocarbon Products Corp., 887 Kinderkamack Rd., P.O. Box 661, River Ridge, NJ 07661 | 012164 |
| Happy Jack, Inc., Snow Hill, NC 28580 | 023851 |

(1) ALPHABETICAL LISTING OF SPONSORS—Continued

| Firm name and address | Drug labeler code |
|---|---|
| Heinold Feeds, Inc., P.O. Box 377, Kouts, IN 46347 | 043727 |
| Henwood Feed Additives, Division of Feed Specialties Co., Inc., 211 Western Rd., Box 577, Lewisburg, OH 45338 | 026186 |
| Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525 | 063604 |
| Hess & Clark, Inc., Seventh and Orange Sts., Ashland, OH 44805 | 050749 |
| Dow B. Hickam, Inc., Pharmaceuticals, P.O. Box 35413, Houston, TX 77035 | 000514 |
| Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059 | 012799 |
| Hoffmann-La Roche, Inc., Nutley, NJ 07110 | 000004 |
| Hubbard Milling Co., 424 North Front St., Mankato, MN 56001 | 012190 |
| ICI Americas, Inc., Wilmington, DE 19897 | 011511 |
| I. D. Russell Co. Laboratories, 1301 Iowa Ave., Longmont, CO 80501 | 017144 |
| I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137 | 050639 |
| Illini Feeds, Box T, Oneida, IL 61467 | 037310 |
| Inhalon Pharmaceuticals, Inc., P.O. Box 21170, Lehigh Valley, PA 18002 | 060307 |
| International Nutrition, Inc., 6664 ''L'' St., Omaha, NE 68117 | 043733 |
| Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966 | 057926 |
| Ivy Laboratories, Inc., 8857 Bond Street, Overland Park, KS 66214 | 021641 |
| J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704 | 039741 |
| Jorgensen Laboratories, Inc., 1450 North Van Buren Ave., Loveland, CO 80538 | 045087 |
| K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214 | 038782 |
| KASCO-EFCO Laboratories, Inc., P.O. Box 730, Hicksville, NY 11802 | 010616 |
| Kerber Milling Co., Box 152, 1817 E. Main St., Emmetsburg, IA 50536 | 029341 |
| Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067 | 063271 |
| Lambert-Kay, A Division of Carter-Wallace, Inc., P.O. Box 1001, Half Acre Rd., Cranbury, NJ 08512-0181 | 011615 |
| Dr. LeGear, Inc., 4161 Beck Ave., St. Louis, MO 63116 | 011950 |
| Lemmon Co., Sellersville, PA 18960 | 000693 |
| Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601 | 061690 |
| Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967 | 010797 |
| M & M Livestock Products Co., Eagle Grove, IA 50533 | 026282 |
| Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525 | 058711 |
| Mallinckrodt Veterinary Operations, Inc., 421 East Hawley St., Mundelein, IL 60060 | 015563 |
| Mattox & Moore, Inc., 1503 East Riverside Drive, Indianapolis, IN 46207 | 027863 |
| McClellan Laboratories, Inc., 19600 Sixth Ave., Lakeview, CA 92353 | 043738 |
| McNeil Laboratories, Inc., Camp Hill Rd., Fort Washington, PA 19034 | 000045 |
| Medicis Dermatologics, Inc., 4343 East Camelback Rd., Suite 250, Phoenix, AZ 85018–2700 | 099207 |
| Med-Pharmex, Inc., Biomed laboratories, 325 East Arrow Hwy., Suite 502, San Dimas, CA 91773 | 051259 |

(1) ALPHABETICAL LISTING OF SPONSORS—Continued

| Firm name and address | Drug labeler code |
|---|---|
| Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077 | 050604 |
| Micro Chemical, Inc., Amarillo, TX 79105 | 047126 |
| Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214 | 059620 |
| Moorman Manufacturing Co., Quincy, IL 62301 | 021930 |
| Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120 | 049968 |
| Nixon and Co., Kiewitt Plaza, Omaha, NE 88501 | 043729 |
| Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland | 055529 |
| Norco Mills of Norfolk, Inc., P.O. Box 56, Norfolk, NE 68701 | 027190 |
| Novartis Animal Health US, Inc. | 058198 |
| Nutra-Blend Corp., P.O. Box 485, Neosho, MO 64850 | 050568 |
| NutriBasics Co., North Highway 71, P.O. Box 1014, WIllmar, MN 56201 | 053740 |
| Nylos Trading Co., Inc., P.O. Box 2, Route 202, Pomona, NY 10970 | 027454 |
| Ohmeda Pharmaceutical Products Division Inc., Liberty Corner, NJ 07938–0804 | 010019 |
| Orion Corp. ORION–FARMOS, P.O. Box 425, SF–20101 Turku, Finland | 052483 |
| Orphan Medical, Inc., 13911 Ridgedale Dr., Suite 475, Minnetonka, MN 55305 | 062161 |
| Osborn Laboratories, Inc., 2d and Oak Sts., Le Sueur, MN 56058 | 012487 |
| OXIS International, Inc., 6040 N. Cutter Circle, Suite 317, Portland, OR 97217–3935 | 024991 |
| Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402 | 028459 |
| Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514 | 055246 |
| Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137 | 053389 |
| Peter Hand Foundation, 2 East Madison St., Waukegan, IL 60085 | 043737 |
| Pfizer, Inc., 235 East 42d St., New York, NY 10017 | 000069 |
| Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199 | 000009 |
| Phoenix Pharmaceutical, Inc., 4621 Easton Rd., P.O. Box 6457 Farleigh Station, St. Joseph, MO 64506–0457 | 057319 |
| Phoenix Scientific, Inc. 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457 | 059130 |
| Planalquimica Industrial Ltda., Rua das Magnolias nr. 2405, Jardim das Bandeiras, CEP 13053–120, Campinas, Sao Paulo, Brazil | 060728 |
| PM Ag Products, Inc., 1055 West 175th St., Homewood, IL 60430 | 036904 |
| PM Resources, Inc., 13001 St. Charles Rock Rd., Bridgeton, MO 63044 | 060594 |
| Premier Malt Products, Inc., Milwaukee, WI 53201 | 032707 |
| Protein Blenders, Inc., Box 631, Highway 218 South, Iowa City, IA 52240 | 033999 |
| Protiva, A Unit of Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167 | 059945 |
| Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812 | 017800 |
| Quali-Tech Products, Inc., 318 Lake Hazeltine Drive, Chaska, MN 55318 | 016968 |
| The Rath Packing Co., P.O. Box 330, Waterloo, IA 50704 | 028260 |
| Rhone Merieux Canada, Inc., 345 Boul. Labbe Blvd., North Victoriaville, QC, G6P 1B1 Canada | 047015 |
| Rhone-Poulenc Chemicals, Ltd., P.O. Box 46, St. Andrews Rd., Avonmouth, Bristol BS11 9YF, England, UK | 059258 |
| Rhone-Poulenc, Inc., P.O. Box 125, Black Horse Lane, Monmouth Junction, NJ 08852 | 011526 |
| A. H. Robins Co., P.O. Box 518, Fort Dodge, IA 50501–0518 | 000031 |
| Roussel-UCLAF SA, Animal Health Division, 102 Route de Noisy, 93235 Romainville Cedex, France | 012579 |
| RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620 | 058670 |
| R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518 | 011014 |
| Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083 | 000061 |
| G. D. Searle & Co., P.O. Box 5110, Chicago, IL 60680 | 000014 |
| Seeco Inc., Box 1014, North Highway 71, Willmar, MN 56201 | 011749 |
| Shell Chemical Co., Division of Shell Oil Co., Animal Health, One Shell Plaza, Houston, TX 77001 | 011461 |
| Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250 | 063112 |
| South St. Paul Feeds, Inc., 500 Farwell Ave., South St. Paul, MN 55075 | 001800 |
| Southern Micro-Blenders, Inc., 3801 North Hawthorne St., Chattanooga, TN 37406 | 049685 |
| Springfield Milling Corp., Vigorena Feeds, Springfield, MN 56087 | 035955 |
| Square Deal Fortification Co., Kouts, IN 46347 | 036108 |
| Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151 | 017153 |
| Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043–4705 | 000402 |
| Sterling Winthrop, Inc., 9 Great Valley Pkwy., Malvern, PA 19355 | 000934 |
| Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752 | 037990 |
| Syntex Animal Health, Division of Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304 | 000033 |
| Teva Pharmaceuticals USA, 650 Cathill Rd., Sellersville, PA 18960 | 000093 |
| Tevcon Ind., Inc., 8904 J St., Omaha, NE 68127 | 011757 |
| Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218 | 000842 |
| Triple ''F,'' Inc., 10104 Douglas Ave., Des Moines, IA 50322 | 011490 |
| Tutag Pharmaceuticals, Inc., 2599 W. Midway Blvd., Broomfield, CO 80020 | 000124 |
| United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220, Madison, WI 53711 | 058639 |
| V.P.O., Inc., 4444 S. 76th St., Omaha, NE 68127 | 043743 |
| Vet-A-Mix, Inc., P.O. Box A, Shenandoah, IA 51601 | 011789 |
| Vetem, S.p.A., Viale E. Bezzi 24, 20146 Milano, Italy. | 055882 |
| Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215 | 000857 |
| Veterinary Service, Inc., 416 North Jefferson St., P.O. Box 2467, Modesto, CA 95354 | 033008 |
| Veterinary Specialties Inc., 387 North Valley Ct., Barrington, IL 60010 | 062925 |
| Walco International, Inc., 15 West Putnam, Porterville, CA 93257 | 049185 |
| Waterloo Mills Co., 2050 Mitchell Ave., Waterloo, IA 50704 | 017139 |

(1) ALPHABETICAL LISTING OF SPONSORS—Continued

| Firm name and address | Drug labeler code |
|---|---|
| Wayne Feed Division, Continental Grain Co., P.O. Box 459, Libertyville, IL 60048 | 034936 |
| Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363 | 035098 |
| Wendt Laboratories , Inc., 100 Nancy Dr., Belle Plaine, MN 56011 | 015579 |
| West Agro, Inc., 11100 N. Congress Ave., Kansas City, MO 64153 | 033392 |
| Westchester Veterinary Products, Inc., 180 Mamaroneck Ave., White Plains, NY 10601 | 043732 |
| Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248 | 050378 |
| Western Serum Co., P.O. Box 7025, Phoenix, AZ 85011 | 011398 |
| Wildlife Laboratories, Inc., 1401 Duff Dr., Suite 600, Fort Collins, CO 80524 | 053923 |
| Wyeth Laboratories, Division American Home Products Corp., P.O. Box 8299, Philadelphia, PA 19101 | 000008 |
| Yoder Feed, Division of Yoder, Inc., Kalona, IA 52247 | 035369 |
| Young's Inc., Roaring Spring, PA 16673 | 035393 |
| Zema Corp., P.O. Box 12803, Research Triangle Park, Durham, NC 27709 | 050906 |

(2) NUMERICAL LISTING OF SPONSORS

| Drug labeler code | Firm name and address |
|---|---|
| 000004 | Hoffmann-La Roche, Inc., Nutley, NJ 07110. |
| 000008 | Wyeth Laboratories, Division American Home Products Corp., P.O. Box 8299, Philadelphia, PA 19101. |
| 000009 | Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199. |
| 000010 | Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Highway, St. Joseph, MO 64502. |
| 000014 | G. D. Searle & Co., P.O. Box 5110, Chicago, IL 60680. |
| 000015 | Bristol Laboratories, Division of Bristol-Myers Co., P.O. Box 4755, Syracuse, NY 13221–4755. |
| 000031 | A. H. Robins Co., P.O. Box 518, Fort Dodge, IA 50501–0518. |
| 000033 | Syntex Animal Health Division of Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304. |
| 000045 | McNeil Laboratories, Inc., Camp Hill Rd., Fort Washington, PA 19034. |
| 000046 | Ayerst Laboratories, Division of American Home Products Corp., 685 Third Ave., New York, NY 10017. |
| 000056 | DuPont Merck Pharmaceutical Co., DuPont Merck Plaza, MR2117, Wilmington, DE 19805. |
| 000061 | Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083. |
| 000069 | Pfizer, Inc., 235 East 42d St., New York, NY 10017. |
| 000074 | Abbott Laboratories, North Chicago, IL 60064. |
| 000093 | Teva Pharmaceuticals USA, 650 Cathill Rd., Sellersville, PA 18960. |
| 000115 | Global Pharmaceutical Corp., Castor and Kensington Aves., Philadelphia, PA 19124. |

(2) NUMERICAL LISTING OF SPONSORS—Continued

| Drug labeler code | Firm name and address |
|---|---|
| 000124 | Tutag Pharmaceuticals, Inc., 2599 W. Midway Blvd., Broomfield, CO 80020. |
| 000161 | Cutter Laboratories, Inc., Fourth and Parker St., Berkeley, CA 94710. |
| 000185 | Eon Labs Manufacturing, Inc., 227-15 North Conduit Ave., Laurelton, NY 11413. |
| 000332 | Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407. |
| 000402 | Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043–4705. |
| 000469 | Fujisawa USA, Inc., Deerfield, IL 60015-2548. |
| 000514 | Dow B. Hickam, Inc., Pharmaceuticals, P.O. Box 35413, Houston, TX 77035. |
| 000591 | Danbury Pharmacal, Inc., 131 West St., Danbury, CT 06810. |
| 000693 | Lemmon Co., Sellersville, PA 18960. |
| 000794 | S. B. Penick & Co., 1050 Wall St. West, Lyndhurst, NJ 07071. |
| 000842 | Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218. |
| 000856 | Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501. |
| 000857 | Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215. |
| 000859 | Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201. |
| 000864 | Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006. |
| 000934 | Sterling Winthrop, Inc., 9 Great Valley Pkwy., Malvern, PA 19335. |
| 000986 | Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285. |
| 001800 | South St. Paul Feeds, Inc., 500 Farwell Ave., South St. Paul, MN 55075. |
| 010019 | Ohmeda Pharmaceutical Products Division, Inc., Liberty Corner, NJ 07938–0804. |
| 010042 | American Cyanamid, Division of American Home Products, P.O. Box 1339, Fort Dodge, IA 50501 |
| 010290 | Franklin Laboratories, Inc., P.O. Box 717, Fort Dodge, IA 50501. |
| 010290 | Franklin Laboratories, P.O. Box 669, Amarillo, TX 79105. |
| 010439 | Furst-McNess Co., Freeport, IL 61032. |
| 010471 | H. Clay Glover Co., Inc., 1001 Franklin Ave., Garden City, NY 11530. |
| 010515 | G. C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201. |
| 010616 | KASCO-EFCO Laboratories, Inc., P.O. Box 730, Hicksville, NY 11802. |
| 010797 | Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967. |
| 011014 | R. P. Scherer North America, P.O. Box 5600, Clearwater, FL 33518. |
| 011398 | Western Serum Co., P.O. Box 7025, Phoenix, AZ 85011. |
| 011461 | Shell Chemical Co., Division of Shell Oil Co., Animal Health, One Shell Plaza, Houston, TX 77001. |
| 011485 | Albion Laboratories, Inc., 101 North Main, Clearfield, UT 84015. |
| 011490 | Triple "F," Inc., 10104 Douglas Ave., Des Moines, IA 50322. |
| 011492 | Cooper U.S.A., Inc., P.O. Box 12338, Research Triangle Park, NC 27709. |

(2) NUMERICAL LISTING OF SPONSORS—Continued

| Drug labeler code | Firm name and address |
|---|---|
| 011509 | Combe, Inc., 1101 Westchester Ave., White Plains, NY 10604. |
| 011511 | ICI Americas, Inc., Wilmington, DE 19897. |
| 011526 | Rhone-Poulenc, Inc., P.O. Box 125, Black Horse Lane, Monmouth Junction, NJ 08852. |
| 011615 | Lambert-Kay, A Division of Carter-Wallace, Inc., P.O. Box 1001, Half Acre Rd., Cranbury, NJ 08512-0181. |
| 011749 | Seeco Inc., Box 1014, North Highway 71, Willmar, MN 56201. |
| 011789 | Vet-A-Mix, Inc., P.O. Box A, Shenandoah, IA 51601. |
| 011825 | Affiliated Laboratories Division, Whitmoyer Laboratories, Inc., 19 North Railroad St., Myerstown, PA 19067. |
| 011950 | Dr. LeGear, Inc., 4161 Beck Ave., St. Louis, MO 63116. |
| 012164 | Halocarbon Laboratories, Division of Halocarbon Products Corp., 887 Kinderkamack Rd., P.O. Box 661, River Ridge, NJ 07661. |
| 012190 | Hubbard Milling Co., 424 North Front St., Mankato, MN 56001. |
| 012487 | Osborn Laboratories, Inc., 2d and Oak Sts., Le Sueur, MN 56058. |
| 012579 | Roussel-UCLAF SA, Animal Health Division, 102 Route de Noisy, 93235 Romainville Cedex, France. |
| 012799 | Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059. |
| 012983 | Allied Pharmacal, Division of K. C. Pharmacal, Inc., 1234 Clay St., North Kansas City, MO 64116. |
| 013959 | Feed Products, Inc., 1000 West 47th Ave., Denver, CO 80211. |
| 015563 | Mallinckrodt Veterinary Operations, Inc., 421 East Hawley St., Mundelein, IL 60060. |
| 015565 | Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234. |
| 015579 | Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011. |
| 016968 | Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318. |
| 017030 | Evsco Pharmaceuticals, An Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310. |
| 017135 | Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013–3928. |
| 017139 | Waterloo Mills Co., 2050 Mitchell Ave., Waterloo, IA 50704. |
| 017144 | I. D. Russell Co. Laboratories, 1301 Iowa Ave., Longmont, CO 80501. |
| 017153 | Squire Laboratories, Inc., 100 Mill St., Revere, MA 02151. |
| 017287 | Chemdex, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215. |
| 017473 | Custom Feed Services Corp., 2100 N. 13th St., Norfolk, NE 68701. |
| 017519 | ADM Animal Health & Nutrition Div., P.O. Box 2508, Fort Wayne, IN 46801–2508. |
| 017762 | Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112. |
| 017790 | Carl S. Akey, Inc., P.O. Box 607, Lewisburg, OH 45338. |
| 017800 | Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812. |
| 017826 | Albers Milling Co., Carnation Bldg., 5045 Wilshire Blvd., Los Angeles, CA 90036. |

(2) NUMERICAL LISTING OF SPONSORS—Continued

| Drug labeler code | Firm name and address |
|---|---|
| 021091 | ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105. |
| 021641 | Ivy Laboratories, Inc., 8857 Bond Street, Overland Park, KS 66214. |
| 021676 | Farmland Industries, Inc., Kansas City, MO 64116. |
| 021780 | Golden Sun Feeds, Inc., 111 South Fifth St., Estherville, IA 51334. |
| 021798 | Gooch Feed Mill Corp., 540 South St., Lincoln, NE 68501. |
| 021930 | Moorman Manufacturing Co., Quincy, IL 62301. |
| 022591 | Grain Processing Corp., Muscatine, IA 52761. |
| 023851 | Happy Jack, Inc., Snow Hill, NC 28580. |
| 024174 | Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464. |
| 024264 | Dawes Laboratories, Inc., 450 State St., Chicago Heights, IL 60411. |
| 024991 | OXIS International, Inc., 6040 N. Cutter Circle, Suite 317 Portland, OR 97217–3935. |
| 025001 | Diamond Shamrock Corp., Nutrition & Animal Health Div., 1100 Superior Ave., Cleveland, OH 44114. |
| 025463 | Altana Inc., 60 Baylis Rd., Melville, NY 11747. |
| 026186 | Henwood Feed Additives, Division of Feed Specialties Co., Inc., 211 Western Rd., Box 577, Lewisburg, OH 45338. |
| 026282 | M & M Livestock Products Co., Eagle Grove, IA 50533. |
| 027190 | Norco Mills of Norfolk, Inc., P.O. Box 56, Norfolk, NE 68701. |
| 027454 | Nylos Trading Co., Inc., P.O. Box 2, Route 202, Pomona, NY 10970. |
| 027863 | Mattox & Moore, Inc., 1503 East Riverside Dr., Indianapolis, IN 46207. |
| 028260 | The Rath Packing Co., P.O. Box 330, Waterloo, IA 50704. |
| 028459 | Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402. |
| 029341 | Kerber Milling Co., Box 152, 1817 E. Main St., Emmetsburg, IA 50536. |
| 030841 | Feed Service Co., Inc., 303 Lundin Blvd., P.O. Box 698, Mankato, MN 56001. |
| 032707 | Premier Malt Products, Inc., Milwaukee, WI 53201. |
| 033008 | Veterinary Service, Inc., 416 North Jefferson St., P.O. Box 2467, Modesto, CA 95354. |
| 033392 | West Agro, Inc., 11100 N. Congress Ave., Kansas City, MO 64153. |
| 033999 | Protein Blenders, Inc., Box 631, Highway 218 South, Iowa City, IA 52240. |
| 034936 | Wayne Feed Division, Continental Grain Co., P.O. Box 459, Libertyville, IL 60048. |
| 035098 | Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363. |
| 035369 | Yoder Feed, Division of Yoder, Inc., Kalona, IA 52247. |
| 035393 | Young's, Inc., Roaring Spring, PA 16673. |
| 035955 | Springfield Milling Corp., Vigorena Feeds, Springfield, MN 56087. |
| 036108 | Square Deal Fortification Co., Kouts, IN 46347. |
| 036904 | PM Ag Products, Inc., 1055 West 175th St., Homewood, IL 60430. |
| 037310 | Illini Feeds, Box T, Oneida, IL 61467. |
| 037990 | Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752. |

(2) NUMERICAL LISTING OF SPONSORS—Continued

| Drug labeler code | Firm name and address |
|---|---|
| 038782 | K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214. |
| 039741 | J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704. |
| 043727 | Heinold Feeds, Inc., P.O. Box 377, Kouts, IN 46347. |
| 043728 | Balfour Guthrie & Co., Ltd., 315 North H St., Fresno, CA 93701. |
| 043729 | Nixon and Co., Kiewitt Plaza, Omaha, NE 88501. |
| 043732 | Westchester Veterinary Products, Inc., 180 Mamaroneck Ave., White Plains, NY 10601. |
| 043733 | International Nutrition, Inc., 6664 L St., Omaha, NE 68117. |
| 043735 | Gland-O-Lac Co., 1818 Leavenworth St., Omaha, NE 68102. |
| 043737 | Peter Hand Foundation, 2 East Madison St., Waukegan, IL 60085. |
| 043738 | McClellan Laboratories, Inc., 19600 Sixth Ave., Lakeview, CA 92353. |
| 043743 | V.P.O., Inc., 4444 South 76th St., Omaha, NE 68127. |
| 043744 | Farmers Feed & Supply Co., Ninth St. at Northwestern Tracks, Tipton, IA 52772. |
| 043781 | Cyanamid Agricultural de Puerto Rico, Inc., P.O. Box 243, Manati, PR 00701. |
| 045087 | Jorgensen Laboratories, Inc., 1450 North Van Buren Ave., Loveland, CO 80538. |
| 045984 | American Veterinary Products, Inc., 749 South Lemay, Suite A3–231, Fort Collins, CO 80524. |
| 046573 | Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024. |
| 046987 | Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501. |
| 047015 | Rhone Merieux Canada, Inc., 345 Boul. Labbe Blvd., North Victoriaville, QC, G6P 1B1 Canada. |
| 047019 | Carnation Co., 5045 Wilshire Blvd., Los Angeles, CA 90036. |
| 047126 | Micro Chemical, Inc., Amarillo, TX 79105. |
| 049047 | Michael Gordon, Inc., P.O. Box 1091, San Francisco, CA 94118. |
| 049185 | Walco International, Inc., 15 West Putnam, Porterville, CA 93257. |
| 049685 | Southern Micro-Blenders, Inc., 3801 North Hawthorne St., Chattanooga, TN 37406. |
| 049968 | Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120. |
| 050378 | Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248. |
| 050568 | Nutra-Blend Corp., P.O. Box 485, Neosho, MO 64850. |
| 050604 | Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077. |
| 050639 | I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137. |
| 050749 | Hess & Clark, Inc., Seventh and Orange Sts., Ashland, OH 44805. |
| 050906 | Zema Corp., P.O. Box 12803, Research Triangle Park, Durham, NC 27709. |
| 050972 | Gossett Nutrition, Inc., 1676 Cascade Dr., Marion, OH 43302. |
| 051212 | Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052. |
| 051259 | Med-Pharmex, Inc., Biomed Laboratories, 325 East Arrow Hwy., Suite 502, San Dimas, CA 91773. |

(2) NUMERICAL LISTING OF SPONSORS—Continued

| Drug labeler code | Firm name and address |
|---|---|
| 051267 | Cooperative Research Farms, Box 69, Charlotteville, NY 12036. |
| 051359 | Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44141. |
| 052483 | Orion Corp. ORION–FARMOS, P.O. Box 425, SF–20101 Turku, Finland. |
| 053389 | Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137. |
| 053501 | Fort Dodge Animal Health, A Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501. |
| 053740 | NutriBasics Co., North Highway 71, P.O. Box 1014, WIllmar, MN 56201. |
| 053923 | Wildlife Laboratories, Inc., 1401 Duff Dr., Suite 600, Fort Collins, CO 80524. |
| 055246 | Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514. |
| 055529 | Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland. |
| 055882 | Vetem, S.p.A., Viale E. Bezzi 24, 20146 Milano, Italy. |
| 057319 | Phoenix Pharmaceutical, Inc., 4621 Easton Rd., P.O. Box 6457 Farleigh Station, St. Joseph, MO 64506–0457. |
| 057561 | Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503. |
| 057926 | Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966. |
| 058034 | John J. Ferrante, 11 Fairway Lane, Trumbull, CT 06611. |
| 058198 | Novartis Animal Health US, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. |
| 058639 | United Vaccines, A Harlan Sprague Dawley, Inc., Co., P.O. Box 4220, Madison, WI 53711. |
| 058670 | RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620. |
| 058711 | Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525. |
| 059079 | Delmarva Laboratories, Inc., 2200 Wadebridge Rd., P.O. Box 525, Midlothian, VA 23113. |
| 059130 | Phoenix Scientific, Inc. 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457 |
| 059258 | Rhone-Poulenc Chemicals, Ltd., P.O. Box 46, St. Andrews Rd., Avonmouth, Bristol BS11 9YF, England, UK. |
| 059945 | Protiva, A Division of Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167. |
| 059521 | Ausa International, Inc., Rt. 8, P.O. Box 324–12, Tyler, TX 75703. |
| 059620 | Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214.Blvd., St. Louis, MO 63167. |
| 060307 | Inhalon Pharmaceuticals, Inc., P.O. Box 21170, Lehigh Valley, PA 18002. |
| 060594 | PM Resources, Inc., 13001 St. Charles Rock Rd., Bridgeton, MO 63044. |
| 060728 | Planalquimica Industrial Ltda., Rua das Magnolias nr. Jardim das Bandeiras, CEP 13053–120, Campinas, Sao Alto, Brazil. |
| 060865 | Anika Research, Inc., 160 New Boston St., Woburn, MA 01801. |
| 060951 | Endo Pharmaceuticals, Inc., 223 Wilmington West Chester Pike, Chadds Ford, PA 19317. |
| 061623 | Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland. |

(2) NUMERICAL LISTING OF SPONSORS—Continued

| Drug labeler code | Firm name and address |
|---|---|
| 061651 | Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland. |
| 061690 | Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601. |
| 062161 | Orphan Medical, Inc., 13911 Ridgedale Dr., Suite 475, Minnetonka, MN 55305. |
| 062408 | Alstoe, Ltd., Animal Health, Granary Chambers, 37–39 Burton St., Melton Mowbray, Leicestershire LE13 1AF, England. |
| 062925 | Veterinary Specialties Inc., 387 North Valley Ct., Barrington, Il 60010. |
| 063075 | Biopure Corp., 11 Hurley St., Cambridge, MA 02141. |
| 063112 | Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250. |
| 063248 | Deprenyl Animal Health, Inc., 7101 College Blvd., Suite 580, Overland Park, KS 66210. |
| 063271 | Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067. |
| 063604 | Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525. |
| 063765 | Akzo Nobel Surface Chemistry AB, Box 851, S–44485 Stenungsund, Sweden. |
| 099207 | Medicis Dermatologics, Inc., 4343 East Camelback Rd., Suite 250, Phoenix, AZ 85018–2700. |

[40 FR 13807, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §510.600, see the List of CFR Sections Affected in the Finding Aids section of this volume.

# PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 360b, 371.

## §511.1 New animal drugs for investigational use exempt from section 512(a) of the act.

(a) *New animal drugs for tests in vitro and in laboratory research animals.* (1) A shipment or other delivery of a new animal drug or animal feed bearing or containing a new animal drug intended solely for tests in vitro or in animals used only for laboratory research purposes shall be exempt from section 512 (a) and (m) of the act if it is labeled as follows:

*Caution.* Contains a new animal drug for investigational use only in laboratory research animals or for tests in vitro. Not for use in humans.

(2) The person distributing or causing the distribution of new animal drugs for tests in vitro or in animals used only for laboratory research purposes under this exemption shall use due diligence to assure that the consignee is regularly engaged in conducting such tests and that the shipment of the new animal drug will actually be used for tests in vitro or in animals used only for laboratory research.

(3) The person who introduced such shipment or who delivered the new animal drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the expert or expert organization to whom the new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department at reasonable times, he shall make such records available for inspection and copying.

(4) The exemption allowed in this paragraph shall not apply to any new animal drug intended for in vitro use in the regular course of diagnosing or treating disease, including antibacterial sensitivity discs impregnated with any new animal drug or drugs, which discs are intended for use in determining susceptibility of microorganisms to the new animal drug or drugs.

(b) *New animal drugs for clinical investigation in animals.* A shipment or other delivery of a new animal drug or an animal feed containing a new animal drug intended for clinical investigational use in animals shall be exempt from section 512(a) and (m) of the act if all the following conditions are met:

(1) The label shall bear the statements:

*Caution.* Contains a new animal drug for use only in investigational animals in clinical trials. Not for use in humans. Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

In the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear the